REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 1-4 and 9-28 were pending in this application when last examined.

Claims 1-4, 9 and 28 were examined on the merits and stand rejected.

Claims 10-27 were withdrawn as non-elected subject matter.

Claims 1-4 and 9 are amended to clarify the claimed invention.

Claim 28 is cancelled without prejudice or disclaimer thereto.

No new matter has been added.

II. CLAIM OBJECTIONS

On pages 19-20 of the Office Action, claim 1 is objected to for informalities. This objection is overcome, as applied to amended claim 1, for reasons which are self-evident.

III. WRITTEN DESCRIPTION/ENABLEMENT REJECTIONS

On pages 5-10 of the Office Action, claims 1-4, 9 and 28 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification lacks written description support.

On pages 10-16, claims 1-4 and 28 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification lacks enablement.

Claim 28 is cancelled in order to expedite prosecution and without acquiescence to the Office's position. Therefore, the rejections to this claim are moot.

In order to expedite prosecution and without acquiescence to the Office's position, claims 1-4 and 9 have been amended to limit the claims to a mammalian cell comprising the *Aspergillus nidulans* AlcR protein and the particular promoter described in the Examples. Applicants note that it was indicated in the on page 10 of the Office Action that such is supported by the specification.

Therefore, Applicants respectfully submit that these rejections are overcome.

IV. OBVIOUSNESS REJECTION

On pages 16-18 of the Office Action, claims 1, 2, 4, 9 and 28 were rejected under 35 U.S.C. § 103(a) as obvious over Caddick et al. (US 6,605,754) in view of White (1999).

On pages 18-19, claims 1 and 3 were rejected under 35 U.S.C. § 103(a) as obvious over Caddick et al. in view of White and further in view of Flipphi et al. (2002).

Claim 28 is cancelled. Therefore, the rejection of this claim is moot.

Applicants respectfully traverse this rejection as applied to the amended claims.

Applicants note that the claims have been amended to limit the claims to a mammalian cell comprising the *Aspergillus nidulans* AlcR protein and the particular promoter described in the Examples.

Caddick et al. (US 6,605,754) in view of White (1999)

Caddick et al. in combination with White does not make obvious the claimed invention since ethanol is not a direct inducer of the AlcR system and would require metabolization into acetaldehyde to be induction effective, which does not occur in standard mammalian cell cultures.

Caddick et al. describes the use of the ethanol-inducible AlcA/AlcR system in tobacco plant cells.

The Office indicates that Caddick et al. discloses a chemically-inducible plant gene expression cassette comprising a first promoter, e.g. the alcA gene promoter (i.e. the alcA gene encodes alcohol dehydrogenase I) operatively linked to a regulator sequence which encodes a regulator protein, e.g. the alcR regulator protein (i.e. the responsive transcription factor), and that said alcR gene product is induced in the presence of an effective exogenous inducer, i.e. by the protein/alcohol or proteine/ketone combination.

The claimed invention is directed to a mammalian cell comprising the AlcR protein and a promoter operatively linked to P_{alcA} operator sites specific for binding the AlcR protein. In the claimed invention, the formation of the AlcR protein is dissected from alcohol dehydrogenase.

Both Caddick et al. and the claimed invention make use of the fact, that the AlcR protein activates expression from alcA by binding to three specific sites in the alcA promoter. Caddick et al. discloses an inducible target gene expression system for plants cells and that suitable

effective chemicals for induction are butan-2-one, cyclohexanone, acetone, butan-2-ol, 3-oxobutyric acid, propan-2-ol, and ethanol (column 4, lines 54-56).

White suggests luciferase expression can be regulated in mammalian cells in response to ethanol by transfection of AlcR fused to a transcriptional activator together with a luciferase expression unit driven by an AlcA-derived promoter. However, White is defective, the proposed system has never been realized and, in the light of recent work, this system is not functional since ethanol is not a direct inducer of the AlcR system (Flipphi et al.) and would rather require metabolization into acetaldehyde to be induction effective, which, does not occur in standard mammalian cell cultures. This is independent of whether ethanol is metabolized to acetaldehyde in liver and brain cells.

Therefore, Caddick et al. alone or in combination with White does not make obvious the claimed invention.

Caddick et al. in view of White and further in view of Flipphi et al. (2002)

A skilled artisan knowing Flipphi et al., Caddick et al. and White would still not arrive at the claimed invention, because there is no indication or hint as to how to construct the particular mammalian cell comprising AlcR protein and the particular P_{alcA} operator site of part b. in claim 1. Flipphi et al. describes isolation of AlcA and AlcR genes and prove that the AlcA/AlcR system is inducible by several primary alcohols, primary monoamines and L-threonine, and corresponding aliphatic aldehydes. Independent of whether acetaldehyde or ethanol or any other alcohol or ketone is used to influence expression or repression, it would not be obvious to a person of skill in the art to construct a mammalian cell comprising AlcR protein and the particular PalcA operator site based on the combination of these references.

For the above-noted reasons, these rejections are untenable and should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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